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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Joseph S. Adorante	)Examiner
Serial No.:	10/017,660	)Fay,
Filed:	12/12/2001	)Zohreh A.
For:	INHIBITION OF NONINACTIVATING Na CHANNELS OF MAMMALIAN OPTIC NERVE DEGENERATION ASSOCIATED WITH GLAUCOMA	)Art Unit 1614

June 2004

RESPONSE

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

In response to an Office Action mailed March 22, 2004, the Applicant traverses the Examiner's rejection as follows:

Claims 23-26 have been rejected by the Examiner under 35 USC 112, first paragraph, as being beyond the scope of the enabling disclosure as to the use of the term "preventing retinal ganglion cell death". The Examiner states that the specification fails to provide guidance to a person skilled in the art to determine as to how the prevention is done.

It has been held that the function of the description requirement is to ensure that the inventor had possession,

as of the filing date of the application, relied upon, of specific subject matter claimed; how the specification accomplishes this is not material; the claimed subject matter need not be described in haec verba to satisfy the description requirements. Nor is it necessary that the application describe the claimed limitations exactly but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that the Applicant had invented the method. See In re Herschler, 200 USPQ, 711, 717(CCPA, 1979).

As set forth in In re Smith and Hubin, 176 USPQ 620, 624 (CCPA, 1973) compliance with the first paragraph of Section 12 is adjudged from the perspective of a person skilled in the relevant art. The specification as originally filed must convey clearly to those skilled in the art the information that the Applicant has invented and the subject matter claimed. When the original specification accomplishes this, regardless of how this is accomplished, the essential goal of the description requirements under 35 USC 112 is realized. See also In re Smythe, 176 USPQ 279. As it pertains to the present invention, the Applicant submits that one skilled in the art is one familiar with phacoemulsification apparatus and, in fact, familiar with the disclosed apparatus.

Therefore, the Applicant submits that the specification as originally filed does convey to those skilled in the art the information as to how to perform the method of the present invention.

The Applicant further submits that the Board of Appeals has stated that the Examiner has the initial burden of presenting evidence, or reasons why persons skilled in the art would not recognize the specification disclosure as the description of the invention defined by the claims. See In re Westheim, 191 USPQ 90 (CCPA, 1976).

In order for the Examiner to reject the claims under the written description requirement of 35 USC 112, first paragraph, the Examiner must present evidence or reasons why a person skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. In re Alton, 37 USPQ 2d 1576, 1583 (U.S. Court of Appeals Federal Circuit, 1996), quoting from In re Wertheim, 191 USPQ 90, 97 (CCPA, 1976). An originally filed application reasonably conveys to those skilled in the relevant art that the Applicant, as of filing date of the original Application, had possession of the claimed invention, satisfies the written description requirement of 112, first paragraph, in order for the Examiner to reject the claims under the enablement requirement of 35 USC 112, first paragraph, the Examiner must present evidence or reasons why the specification does not teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation". In re Wright, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993). As long as "undue experimentation" is not involved, a specification would comply the enablement requirement of the statute even if a reasonable amount of routine experimentation is necessary to practice the claimed invention. Enzo Biochem, Inc. v. Calgene, 53 USPQ 2d 1129, 1135 (Fed. Cir. 1999). Such as the case at hand, the Examiner has not shown why

undue experimentation is required. The Examiner should provide an analysis of the legal test of "undue experimentation" and specifically discuss the underline factual inquiries adopted in In re Wands, 8 USPQ 2d 1400 (CAFC, 1988) in order to support a rejection under the enablement requirement of 35 USC 112, first paragraph.

In addition, the Examiner must explicitly set forth how the claims are being interpreted. The review of the grounds of rejection of the claims necessarily entails the interpretation of the scope of the claims. In re Morris, 44 USPQ 2d 1023, 1027 (Fed. Cir. 1997).

The claims subject matter relates to a method for preventing a retinal ganglion cell death. The Examiner has stated that there is no working examples, however the Applicant has set forth specific examples of the sodium channel blockers which are used as the active effective ingredient in the ophthalmic compositions of the present invention and provided a demonstrating example beginning on page 12 of the original specification.

Accordingly, the Applicants submit that undue experimentation is not required and the Examiner has not provided convincing evidence to the contrary.

Accordingly, the Applicants respectfully request the Examiner to withdraw the rejection of claims 23-26 under 35 USC 112, first paragraph.

Claims 23-26 have also been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 5,403,861

to Goldin, et al. In this rejection, the Examiner has stated that the use of the claimed compounds for any reason in the body would inherently prevent the retinal ganglion cell death. The Applicants submits that the Examiner has not substantiated this statement by either the cited Goldin, et al. reference or further documentation that any use of the compound in the body would inherently prevent the retinal ganglion cell death. In fact, Goldin, et al. emphasizes the criticality of the administration of the drug. See paragraph 32 of Goldin, et al. wherein it is stated "numerous studies have emphasized the importance of administration of neuro-protective drugs …".

Furthermore, if the Examiner's statements were true, the topical application of a medicament on a toe would inherently prevent retinal ganglion cell death.

Accordingly, the Applicant submits that the Examiner's remarks and conclusion are not well taken with regard to the Applicants allegation of criticality to the different use of the claimed invention compared to the prior art of record.

Accordingly, with reliance on arguments hereinbefore presented and an amendment filed April 22, 2003, the Applicant submits that a rejection under 35 USC 102(b) on the basis of the Goldin, et al. reference is not sustainable and accordingly request the Examiner to withdraw the rejection.

In view of the arguments hereinabove set forth it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,

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